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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,711

02/07/2006

Barbara Bertani

P33150

7489

20462

7590

09/15/2008

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER

HABTE, KAHSAI

ART UNIT

PAPER NUMBER

1624

NOTIFICATION DATE

DELIVERY MODE

09/15/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/535,711	BERTANI ET AL.	
	Examiner	Art Unit	
	Kahsay T. Habte	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-13, 15, 16, 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-11, 13, 15, 16, 21 and 22 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/20/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 3-13, 15-16 and 21-22 are pending in this application.

Election/Restriction

2. Applicant's election with traverse of a single disclosed species: 4-Methyl-6-{2-[4-(2-methylquinolin-5-yl)piperazin-1-yl]ethyl}-4H-benzo[1,4]oxazin-3-one is acknowledged.

The traversal is on the ground(s) that the "present application was filed under the provisions of 35 § U.S.C. 371 and the present election/restriction requirement is not in accordance with the unity of invention". The examiner disagrees with applicant's argument. The claimed species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the special technical feature of most of the species recited in claim 12 is different one from the other because of the various definitions of variables A, X and q. The search for the invention without the restriction would impose undue burden on the examiner. Note that the search for the compounds using Chemical Abstract Database did not go to completion.

Examination of all species would require search for different core structures in the CAS databases and also in commercial databases available at USPTO. Therefore, examination of all species would require a serious additional burden of search.

The requirement is still deemed proper and is therefore made FINAL.

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Note that the examiner searched the elected species and found no prior art. The search around the elected species was expanded and stopped when a prior art was found. The examiner recommends that applicants recite specific rings for the definition of A to overcome any prior art rejection under 102(b) or obviousness type rejection under 103(a).

3. The claims are drawn to multiple inventions for reasons set forth in the restriction requirement. The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter is recommended in response to this Office Action. It is required that applicants delete any definition of variable R3 that makes the second ring bicyclic or R3 connected to other end of the chain to an available carbon atom in Z. Note that the elected species is a monocyclic ring (piperazine) and the definition of Z is a chain and not a ring.

Information Disclosure Statement

4. Applicant's Information Disclosure Statement, filed on 05/20/2005 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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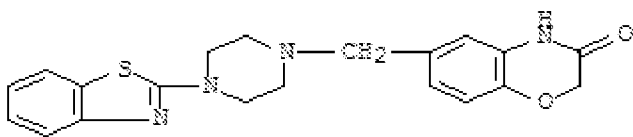
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-4, 6-7, 15-16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Belliotti et al. U.S. Pat. No. 6,177,422. Cited reference at column 3 (lines 22-23) discloses the following compound shown below that is the same as applicants when applicant' formula (Ia) has the following substituents:

A = benzoxazole (6,5 heteroaromatic group); X = N; q = 1; p = 0; R1 = H; R3 = H; and Z = -CH₂-.

BN 200194-67-8 CAPLUS
CN 2H-1,4-Benzoxazin-3(4H)-one, 6-[[4-(2-benzothiazolyl)-1-piperazinyl]methyl]- (CA INDEX NAME)



Since the compound is the same as applicants, the prior art rejection under 102(b) is proper.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. A method of treatment of a serotonin-related disorder is recited, but the specification is not enabled for such a scope.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The scope of the claims is not adequately enabled solely based on the serotonin activity disclosed at page 1 of the specification. First, the instant claims cover 'diseases' that are known to exist and those that may be discovered in the future, for which there is no enablement provided. The use disclosed in the specification is as medicaments used in the treatment of CNS and "other disorders". There is no working example or data that correlates to the treatment of the diverse disorders embraced the instant claims. The disorders encompassed by the instant claims (e.g. CNS or "other disorders", some of which have been proven to be extremely difficult to treat. Note that

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CNS by itself is very broad in nature and the claim also covers the treatment of various disorders that are known or unknown. The instant claim 21 recites, "A method for the treatment of a serotonin-related disorder", but said claim appear to be a 'reach through' format. Reach through claims, in general have a format drawn to mechanistic, receptor binding or enzymatic functionality and thereby reach through any or all diseases, disorders or conditions, for which they lack written description and enabling disclosure in the specification thereby requiring undue experimentation for one of skill in the art to practice the invention. There is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note *In re Surrey*, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the use of the invention. In view of the breadth of the claim, the chemical nature of the invention, the unpredictability of ligand-receptor interactions in general, and the lack of working examples regarding the activity of the claimed compounds, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-11, 13, 15-16 and 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 3, the phrase “A is bicyclic 6,5 or 6,6 heteroaromatic group” is indefinite. What is covered and what is not? What are the types of heteroatoms present in the bicyclic ring? How many heteroatoms can be present in the bicyclic ring? It is recommended that applicants recite specific rings as it was done in claim 11 to overcome this rejection.

b. In claim 3, the phrase “R3..(b) forms a bridge across the ring” is not clear. What bridge is formed across the ring?

Objection

8. Claim 12 is objected to as being dependent upon a rejected base claim, but might be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kahsay T. Habte/
Primary Examiner, Art Unit 1624

KH
September 11, 2008